

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

co/c



In re the application of: Blake Pepinsky *et al.*

Docket No.: 14937.0059

Filed: April 11, 2001

Issued: November 8, 2005

Serial No.: 09/832,658

Patent No.: 6,962,978 B2

For: *POLYMER CONJUGATES OF INTERFERON BETA-1A AND USES*

**ATTN: Certificate of Correction Branch  
United States Patent and Trademark Office  
Customer Service Window  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314**

**REQUEST FOR EXPEDITED ISSUANCE OF CERTIFICATE OF CORRECTION**

**PURSUANT TO 37 C.F.R. 1.322**

Applicants respectfully request that a Certificate of Correction be issued to correct typographical errors in the claims of the above mentioned patent. The errors were incurred by the U.S. Patent and Trademark Office. A copy of the allowed claims and a copy of the Issue Classification indicating the renumbering of those claims as issued in U.S. Patent No. 6,962,978 are attached at Exhibit A.

With respect to claim 3 (original claim 5), col. 53, line 55 of the '978 patent misspells the word "inlerferon." See attached original claims at p. 2 for support for this correction. With respect to claim 5 (original claim 7), col. 53, line 61 of the '976 patent, the word "ED" is used instead of "ID." See attached original claims at p. 2 for support for this correction. With respect to claim 9 (original claim 11), col. 54, line 59 of the '978 patent omits the word "of" from the claim. See attached original claims at p. 3 for support for this correction. With respect to claim 12 (original claim 15), col. 54, line 66 of the '978 patent, misspells the word "psyiologically." See attached original claims at p. 3 for support for this correction. With respect to claim 12 (original claim 15), col. 55, line 2 in the '978 patent, omits a comma from the phrase "alklyene glycol moiety, wherein the physiologically active." See attached original claims at p. 3 for support for this correction.

**Certificate  
JAN 12 2009  
of Correction**

**JAN 12 2009**

A Certificate of Correction form, PTO/SB/44 is also submitted herewith.

Applicants do not believe that any fees are due with the filing as the error in the claims was incurred by the USPTO. However, should any fees be required by this request, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

Date: 1-8-09

  
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## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 6,962,978 B2  
APPLICATION NO. : 09/832,658  
ISSUE DATE : NOVEMBER 8, 2005  
INVENTOR(S) : PEPINSKY *et al.*

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 53, line 55, the text "is an inlerferon-beta-1a" should read -- is an interferon-beta-1a --.

Column 53, line 61, the text "SEQ ED NO: 26" should read -- SEQ ID NO: 26 --.

Column 54, line 59, the text "moiety the interferon-beta-1a fusion protein" should read -- moiety of the interferon-beta-1a fusion protein --.

Column 54, line 66, the text "comprising a pysiologically active glycosylated interferon-beta-1a" should read -- comprising a physiologically active glycosylated interferon-beta-1a --.

Column 55, line 2, the text "alkylene glycol moiety wherein the physiologically active" should read -- alkylene glycol moiety, wherein the physiologically active --.

MAILING ADDRESS OF SENDER:


PATENT No. 6,962,978 B2

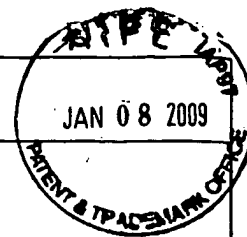
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**JAN 12 2009**

# Exhibit A

JAN 12 2009

<b>Issue Classification</b> 	Application No.	Applicant(s)	
	09/832,658	PEPINSKY ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	



ISSUE CLASSIFICATION									
ORIGINAL					CROSS REFERENCE(S)				
CLASS		SUBCLASS			CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)			
530		351			530	395	402		
INTERNATIONAL CLASSIFICATION					514	12			
C	0	7	K	14/52	424	85.6			
C	0	7	K	14/555	930	142			
A	6	1	K	38/21					
				/					
				/					

FOZIA HAMUD 09/29/03 (Assistant Examiner) (Date)				Total Claims Allowed: 24	
(Legal Instruments Examiner) (Date)		(Primary Examiner) (Date)		O.G. Print Claim(s) 1	O.G. Print Fig. none

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant				<input type="checkbox"/> CPA				<input type="checkbox"/> T.D.				<input type="checkbox"/> R.1.47			
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original		
1	1		31		61		91		121		151		181		
2	2		32		62		92		122		152		182		
			33		63		93		123		153		183		
			34		64		94		124		154		184		
3	5		35		65		95		125		155		185		
4	6		36		66		96		126		156		186		
5	7		37		67		97		127		157		187		
8	8		38		68		98		128		158		188		
	9		39		69		99		129		159		189		
	10		40		70		100		130		160		190		
9	11	6	41		71		101		131		161		191		
10	12	7	42		72		102		132		162		192		
11	13	19	43		73		103		133		163		193		
	14	20	44		74		104		134		164		194		
12	15	21	45		75		105		135		165		195		
	16	22	46		76		106		136		166		196		
	17	23	47		77		107		137		167		197		
13	18	24	48		78		108		138		168		198		
14	19		49		79		109		139		169		199		
15	20		50		80		110		140		170		200		
	21		51		81		111		141		171		201		
16	22		52		82		112		142		172		202		
17	23		53		83		113		143		173		203		
18	24		54		84		114		144		174		204		
	25		55		85		115		145		175		205		
	26		56		86		116		146		176		206		
	27		57		87		117		147		177		207		
	28		58		88		118		148		178		208		
	29		59		89		119		149		179		209		
	30		60		90		120		150		180		210		

JAN 12 2009  
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(SEQ ID NO:26), A2 (SEQ ID NO:27)), B (B1 (SEQ ID NO:31), B2 (SEQ ID NO:32), C (C1 (SEQ ID NO:33), C2 (SEQ ID NO:34)), D (SEQ ID NO:37), E (SEQ ID NO:40)) and loops (AB1 (SEQ ID NO:28), AB2 (SEQ ID NO:29), AB3 (SEQ ID NO:30), CD1 (SEQ ID NO:35), CD2 (SEQ ID NO:36), DE1 (SEQ ID NO:38), DE2 (SEQ ID NO:39)) of interferon-beta-1a (SEQ ID NO: 25). See Example 1

Please replace the pending sequence listing with the enclosed sequence listing.

**In the claims:**

Please cancel claims 25-40 without prejudice or disclaimer as drawn to a non-elected invention. Please amend claims 1, 5, 7-8, 15, 19 and 22, cancel claims 3-4, 9-10, 14, 16, 17 and 21, add new claims 41-48 and replace the pending claims with the following claims:

1. (Amended) A composition comprising the glycosylated interferon-beta-1a of SEQ ID NO: 25 coupled to a non-naturally-occurring polymer at an N-terminal end of said glycosylated interferon-beta-1a, said polymer comprising a polyalkylene glycol moiety.

2. The composition of claim 1, wherein the polyalkylene moiety is coupled to the interferon-beta by way of a group selected from an aldehyde group, a maleimide group, a vinylsulfone group, a haloacetate group, plurality of histidine residues, a hydrazine group and an aminothioli group.

3. (Amended) The composition of claim 1, wherein the interferon-beta-1a of SEQ ID NO: 25 is an interferon-beta-1a fusion protein.

4. The composition of claim 3, wherein the interferon-beta-1a fusion protein comprises a portion of an immunoglobulin molecule.

5. (Amended) A composition comprising the glycosylated interferon-beta-1a of SEQ ID NO: 26 coupled to a non-naturally-occurring polymer at the N-terminus of said glycosylated interferon-

beta-1a, said polymer comprising a polyalkylene glycol moiety.

8 (Amended) A physiologically active interferon-beta composition comprising a physiologically active interferon-beta-1a comprising the amino acid sequence of SEQ ID NO: 25 coupled to a polymer comprising a polyalkylene glycol moiety, wherein the interferon -beta- 1a is coupled to the polymer at a site on the interferon-beta-1a that is an N- terminal end, wherein the physiologically active interferon -beta 1a and the polyalkylene glycol moiety are arranged such that the physiologically active interferon-beta-1a in the physiologically active interferon -beta composition has an activity at least 2-fold greater relative to physiologically active interferon-beta-1b, when measured by an antiviral assay.

11. The composition of claim 8, wherein the interferon -beta-1a is coupled to the polymer at a site by way of a glycan moiety of the interferon -beta-1a.

12. The composition of claim 8, wherein the interferon-beta-1a is an interferon-beta-1a fusion protein.

13. The composition of claim 12, wherein the interferon-beta-1a fusion protein comprises a portion of an immunoglobulin molecule.

16 (Amended) A physiologically active interferon-beta composition comprising a physiologically active glycosylated interferon-beta-1a comprising the amino acid sequence of SEQ ID NO: 25 N-terminally coupled to a polymer comprising a polyalkylene glycol moiety, wherein the physiologically active interferon-beta-1a and the polyalkylene glycol moiety are arranged such that the physiologically active interferon-beta-1a in the physiologically active interferon-beta composition has equal activity relative to physiologically active interferon-beta lacking said moiety, when measured by an antiviral assay.

18. The composition of claim 16, wherein the interferon -beta is coupled to the polymer at a site by way of a glycan moiety on the interferon-beta.

13  
10. (Amended) The composition of claim 1, wherein the interferon-beta-1a is an interferon beta fusion protein.

15  
11. The composition of claim 19, wherein the interferon beta fusion protein comprises a portion of an immunoglobulin molecule.

17 16  
12. (Amended) A stable, aqueously soluble, conjugated interferon-beta-1a complex comprising a interferon-beta-1a comprising the amino acid sequence of SEQ ID NO: 25 N-terminally coupled to a polyethylene glycol moiety, wherein the interferon-beta-1a is coupled to the polychylene glycol moiety by a labile bond, wherein the labile bond is cleavable by biochemical hydrolysis and/or proteolysis.

13 17  
13. A interferon-beta composition according to claims 1, 15 or 12, wherein the polymer has a molecular weight of from about 5 to about 40 kilodaltons.

18  
14. A pharmaceutical composition comprising the interferon-beta composition of claim 23.

6  
15. (New) The composition of claim 1, wherein the glycosylated interferon-beta-1a of SEQ ID NO: 26 is an interferon-beta-1a fusion protein.

70  
16. (New) The composition of claim 1, wherein the interferon-beta-1a fusion protein comprises a portion of an immunoglobulin molecule.

17  
17. (New) A physiologically active interferon-beta composition comprising a physiologically active interferon-beta-1a comprising the amino acid sequence of SEQ ID NO:26 coupled to a non- naturally-occurring polymer at the N-terminus of said glycosylated interferon-beta-1a, said polymer comprising a polyalkylene glycol moiety wherein the physiologically active interferon-beta-1a and the polyalkylene glycol moiety are arranged such that the physiologically active interferon-beta-1a in the physiologically active interferon-beta composition has an activity at



least 2-fold greater relative to physiologically active interferon-beta-1b, when measured by an antiviral assay.

23  
44. (New) The composition of claim 43, wherein the interferon-beta-1a is an interferon-beta-1a fusion protein.

24  
45. (New) The composition of claim 44, wherein the interferon-beta-1a fusion protein comprises a portion of an immunoglobulin molecule.

22  
46. (New) A physiologically active interferon-beta composition comprising a physiologically active glycosylated interferon-beta-1a, comprising the amino acid sequence of SEQ ID NO: 25, N-terminally coupled to a polymer comprising a polyalkylene glycol moiety, wherein the physiologically active interferon-beta-1a and the polyalkylene glycol moiety are arranged such that the physiologically active interferon-beta-1a in the physiologically active interferon-beta composition has equal activity relative to physiologically active interferon-beta lacking said moiety, when measured by an antiviral assay.

23  
47. (New) The composition of claim 46, wherein the interferon-beta-1a is an interferon beta fusion protein.

24  
48. (New) The composition of claim 47, wherein the interferon beta fusion protein comprises a portion of an immunoglobulin molecule.